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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,214	02/11/2002	Lennart Hansson	HANSSON 3A	9275
1444	7590	09/22/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			BERTOGGIO, VALARIE E	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,214	HANSSON ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,11-13,15,20,29,30,32-35,44-51 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 44-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,11-13,15,20,29,30,32-35 and 63 is/are rejected.
- 7) ☒ Claim(s) 1,2,11-13,15,20,29,30,34 and 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/08/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/05/2004 has been entered.

Claims 1,2,11-13,29,30 and 63 have been amended. Claims 3-10,14,16-19,21-28,31,36-43,52-62 and 64-69 have been cancelled. Claims 44-51 are withdrawn. Claims 1,2,11-13,15,20,29,30,32-35,44-51 and 63 are pending and claims 1,2,11-13,15,20,29,30,32-35 and 63 are currently under consideration.

Claim Objections

Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 is drawn to the non-human mammal of claim 1 wherein the mammal exhibits an abnormal skin phenotype. This phenotype is broader and fails to further limit the phenotypes listed in claim 1.

Claims 1,2,11-13,15,20,29 and 30 are objected to because the claims inconsistently interchange the terms "non human" and non-human. "Non-human" is preferred.

Claims 34 and 35 are objected to because they are grammatically incorrect. The claims should read "mouse ovum" (claim 34, line 2) and "mouse ova" (claim 35, line 2) rather than "mice ovum" and "mice ova", respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 1,2,20,29,30,32-35 and 63 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendments to the claims.

The rejection of claims 1,2,4,11-13,15,29,30,32-35 and 63 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The specification, while being enabling for a transgenic mouse whose genome comprises a transgene encoding a heterologous nucleotide sequence coding for human stratum corneum chymotryptic enzyme (SCCE) operably linked to the SV40 early promoter wherein said mouse displays epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction of the skin, and while being enabling for a method of making the mouse using a mouse embryonic stem cell, mouse oocyte or mouse blastocyst, does not reasonably provide enablement for the claimed transgenic mouse wherein the SCCE gene is operably linked to any SV40 promoter or methods of making the mouse wherein any mouse cell type is used. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant's arguments have been fully considered and are persuasive with respect to the previous enablement rejection set forth on pages 7-14 of the previous office action mailed 10/07/2003 with the exception of claim 20. New grounds of rejection appear below.

The claims were previously rejected on the basis that the specification fails to support using any promoter other than an SV40 promoter because the activity of various promoters is unpredictable in the transgenic art (refer to pages 8-9 of the office action mailed 02/13/2003; Hammer, 1990; Mullins, 1996). Applicant has since limited the scope of the claims to a SV40 promoter. The claims now encompass the SV40 early promoter and the SV40 late promoter. However, after further examination, it is noted that the instant specification teaches using only the SV40 early promoter, which differs from other SV40 promoters encompassed by the claims. The specification does not teach using any SV40 promoter other than the SV40 early promoter. The specification has also set forth the unpredictability of promoter activity in demonstrating the unexpected specificity of a normally ubiquitously expressed SV40 early promoter in the skin, resulting in the claimed phenotypes (page 11, lines 27-33). Furthermore, the specification has also disclosed that the keratin 14 promoter expected to drive scce gene expression in more basal cell layers of the skin did not yield the expected results (page 10, line 25-page 11, line 2). The art at the time of filing taught differences in the SV40 early and late promoters, highlighting differences in control and temporal expression pattern. For example, the early promoter is expressed in the lytic part of the SV40 viral life cycle whereas the late promoter is not (refer to Wiley, 1993, Genes and Development, Vol. 7, pages 2206-2219; Tjian, 1981, Initiation Signals

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in Viral Gene Expression, Springer-Verlag, pages 5-24). Therefore, it cannot be predicted in light of the teachings in the art and the specification, that use of any promoter or any SV40 promoter other than the SV40 early promoter would result in the necessary scce expression pattern to obtain the claimed phenotype. Because the specification fails to provide the guidance necessary to overcome this unpredictability, it would require one of skill in the art undue experimentation to determine how to make the mouse broadly encompassed by the claims such that it exhibits the claimed phenotypes.

Claim 20 is not enabled as the specification fails to enable any abnormal skin phenotype as claimed. As set forth on pages 8-12 of the office action mailed 02/13/2003, the phenotype of transgenic mice is unpredictable. The specification teaches generating the claimed mice wherein the mice exhibit epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction of the skin. The specification does not teach how to make the claimed mice such they exhibit any abnormal skin phenotype as encompassed by claim 20. Because the specification fails to provide the guidance necessary to overcome the unpredictability of phenotype in transgenic mice, it would require one of skill in the art undue experimentation to determine how to make the claimed mouse such that it exhibits any abnormal skin phenotype other than epidermal hyperplasia and hyperkeratosis and a mild cellular inflammatory reaction of the skin.

Claims 29,30,32-35 are not enabled as claimed because the claims encompass using any type of mouse cell to create a mouse. The specification teaches generating the claimed mouse by injecting the heterologous nucleotide sequence into mouse embryos (page 27, lines 19-20). The claims encompass microinjecting the sequence into any mouse cell, isolated or as part of an embryo or animal, and using that cell or its progeny to make another mouse. It was well known

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in the art at the time of filing, that a transgenic mouse can be made through a number of different methods including well-established methods of introducing a transgene into a mouse ES cell and using the progeny of the ES cell to generate a mouse by blastocyst injection, injection of DNA into a mouse blastocyst, or introducing the transgene into a mouse oocyte among other less established methods including somatic cell nuclear transfer (refer to Vilotte, 1998, Journal of Mammary Gland Biology, Vol. 3, pages 351-362, specifically, page 352). With respect to using somatic cell nuclear transfer, different cell types have varying capacities for promoting full-term development upon nuclear transfer into an oocyte (Wakayama, 1998, Nature Vol. 394, pages 369-374, specifically, page 373, col.1, paragraph 2). The specification only teaches injection into an embryo and does not even contemplate any other methods encompassed by the claims.

Therefore, in light of the unpredictability and undeveloped nature of the art of making transgenic mice using mouse cell types other than oocytes, blastocysts and totipotent ES cells, and in light of the lack of guidance in the specification with respect to methods of making transgenic mice, it would require undue experimentation for one of skill in the art at the time of filing to make the claimed mouse using any mouse cell type as encompassed by the claims.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,11-13,15,20,29,30,32-35 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is unclear because of the phrase "A non human transgenic mammal which is a mouse". It is unclear if the claim is defining a non-human transgenic mammal as a mouse or if it is limiting the claimed non-human transgenic mammal to a mouse. Claims 2,11-13,15,20,29,30,32-35 and 63 depend from claim 1.

Claim 29 is unclear because of the phrase "non-human cell from a mouse" in step (b). The claim infers that mice have human cells. Mice do not have any human cells or any other non-mouse cells so it is unclear what the claim is referring to. Claims 30 and 32-35 depend from claim 29.

Claims 32 and 33 recite the limitation "the SCCE construct" in line2. There is insufficient antecedent basis for this limitation in the claim.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632

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